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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,465	08/19/2003	Dan M. Granoff	2300-1238.11 PP01238.115	4108
27476	7590	12/15/2004	EXAMINER	
Chiron Corporation Intellectual Property - R440 P.O. Box 8097 Emeryville, CA 94662-8097			DEVI, SARVAMANGALA J N	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/643,465

Applicant(s)

GRANOFF ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-14 ~~is~~/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-14 ~~is~~/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 081903.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Preliminary Amendment

- 1) Acknowledgment is made of Applicants' preliminary amendment filed 08/19/2003.

With this, Applicants have amended the specification including the title.

Status of Claims

- 2) Claims 1-10 and 15-34 have been canceled via the amendment filed 08/19/03.

Claim 11 has been amended via the amendment filed 0/19/03.

Claims 11-14 are pending and are under examination. An Action on the Merits for these claims is issued.

Sequence Listing

- 3) Acknowledgment is made of Applicants' Sequence Listing filed 08/19/2003, which has been entered in the case.

Information Disclosure Statement

- 4) Acknowledgment is made of Applicants' Information Disclosure Statement filed 07/23/2001. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Priority

- 5) The instant application is a Divisional application of application SN 09/910,552, filed 07/23/2001, *now US 6,642,354*, which is a Divisional application of SN 09/494,822, filed 01/31/00, *now abandoned*, which is a Continuation of application SN 08/925,002, filed 08/27/97, *now US patent 6,048,527*, which claims domestic priority to the provisional application, SN 60/025,799, filed 08/27/1996.

Specification - Informalities

- 6) The instant specification is objected to for the following reason(s):

(a) The amendment introduced to the first paragraph of the specification via the preliminary amendment filed 08/19/2003 does not accurately reflect the current status of the prior applications, as indicated above under 'Priority'. Amendment to the first paragraph of the specification is needed to reflect the current status of the prior applications.

(b) The use of trademarks in the instant specification has been noted in this application.

For example, see line 15 on page 68: 'IsoVitalex'; line 32 on page 65: 'Sorvall'; line 28 on page 58, and lines 18 and 19 on page 79: 'Sigma'; and line 32 on page 79: 'Polytron'. The recitation(s) should be capitalized wherever they appear and be accompanied by the generic terminology. Each letter of the trademark must be capitalized. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to the trademarks, wherever such recitations appear.

Double Patenting

7) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970) and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. 3.73(b).

8) Claim 11 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claim 35 of the co-pending application SN 10/121,456. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method for isolating a molecular mimetic of a serogroup B meningococcal epitope of claim 35 of the co-pending application falls within the scope of the instant claim 11.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented. 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

9) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

10) Claims 11-14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 11 has improper antecedence in the recitation 'the complexes' (see last line), because the earlier recitation in the claim is of 'a complex', but not of 'complexes'. Correction is requested.

(b) Claim 11 is vague and indefinite in the limitation: 'derivative', because it is unclear what is encompassed in this claim. What constitutes a derivative, and how much of the capsular polysaccharide's original structure has to be retained such that the resulting product can be considered as a 'derivative', is not clear. The metes and bounds of the structure encompassed in the limitation 'derivative' are indeterminate.

(c) Claim 15 is vague and indefinite in the recitation 'autoreactive' (see line 8), because it is unclear what is encompassed in this limitation. It is not clear what degree of reactivity or cross-reactivity qualifies as 'autoreactivity'. Furthermore, reactivity or non-reactivity with what substance renders the recited antibody 'autoreactive' is unclear.

(d) Claim 11 is vague and indefinite in the recitation 'antibody directed against' because it is unclear whether or not the antibody is specific to a *Neisseria meningitidis* serogroup B capsular polysaccharide derivative.

(e) Claim 11 is vague and indefinite in the recitation: 'method of isolating a molecular mimetic (c) separating the complexes from non-bound molecules'. It is unclear how separating complexes of an antibody and a population of molecules from non-bound molecules as recited in the last step of the claimed method results in a 'method of isolating a molecular mimetic'. Does it mean that an isolated molecular mimetic is a complex of the recited and the population of molecules?

(f) Claims 12-14 are also rejected as being vague and indefinite because of the vagueness or indefiniteness identified above in the base claim.

Rejection(s) under 35 U.S.C. § 102

11) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12) Claim 11 is rejected under 35 U.S.C. § 102(b) as being anticipated by Jennings *et al.* (*J. Exp. Med.* 165: 1207-1211, 1987 - Applicants' IDS) as evidenced by Seid (US 6,638,513).

Jennings *et al.* taught a method of providing molecules of N-propionylated group B meningococcal capsular polysaccharides (N-Pr-GBMP) and contacting the N-Pr-GBMP with antibodies specific to an N-propionylated group B meningococcal capsular polysaccharide derivative which antibodies did not cross-react with the native GBMP (i.e., non-autoreactive antibodies) under the conditions of a precipitation test that allow immunological binding between the antibodies and the N-Pr-GBMP molecules to form the precipitates, i.e., complexes, and separating the precipitates or complexes from non-bound molecules by centrifugation (see page 1208, first full paragraph). Jennings *et al.* taught that the N-Pr-GBMP molecules serve as mimics (i.e., molecular mimetics) of a unique epitope of serogroup B *Neisseria meningitidis* (see title; page 1207; and summary). That the prior art N-Pr-GBMP-specific antibodies specific to a unique epitope of serogroup B *Neisseria meningitidis* are non-autoreactive in that the antibodies do not elicit an autoimmune response is inherent from the teachings of Jennings *et al.* in light of what is well known in the art. For instance, Seid disclosed that antibodies specific to a unique epitope of serogroup B *Neisseria meningitidis* that reacts with N-Pr-GBMP-specific antibodies are non-cross reacting with host tissues and with the human neuroblastoma cell line CHP-134, i.e., non-autoreactive antibodies. See first full paragraph in column 5; claims; and paragraph bridging columns 11 and 12.

Claim 11 is anticipated by Jennings *et al.* Seid is not used as a secondary reference in combination with Jennings *et al.*, but rather is used to show that every element of the claimed subject matter is disclosed by Jennings *et al.* See *In re Samour* 197 USPQ 1 (CCPA 1978).

Remarks

13) Claims 11-14 stand rejected.

14) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses and/or papers is (703) 872-9306.

15) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.45 a.m to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

December, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER